



Docket No.: OSTEONICS 3.0-323
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Storer et al.

Application No.: 10/054,363

Group Art Unit: 3732

Filed: November 13, 2001

Examiner: Not Yet Assigned

For: PROSTHETIC IMPLANT CEMENT
DEFLECTOR AND METHOD OF
IMPLANTATION

CLAIM FOR PRIORITY AND SUBMISSION OF DOCUMENTS

Commissioner for Patents
Washington, DC 20231

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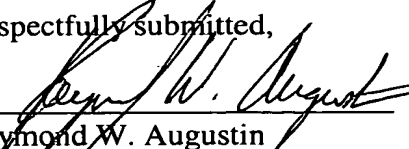
Applicant hereby claims priority under 35 U.S.C. 119 based on the following
prior foreign application filed in the following foreign country on the date indicated:

<u>Country</u>	<u>Application No.</u>	<u>Date</u>
Great Britain	GB-A-00 27893.7	November 15, 2000

In support of this claim, a certified copy of the original foreign application is filed
herewith.

Dated: April 4, 2002

Respectfully submitted,

By 
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I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

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Dated

5 NOV 2001



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GB0027893.7

By virtue of a direction given under Section 30 of the Patents Act 1977, the application is proceeding in the name of

BENOIST GIRARD SAS, Incorporated in France,
203 Boulevard de la Grande Delle B.P.8,
14201 Herouville-Saint-Clair Cedex,
France

[ADP No. 08098337001]

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The
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Request for grant of a patent

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SECTION 30 (1977 ACT) APPLICATION FILED

3/201
15 NOV 2000

The Patent Office

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Gwent NP9 1RH

1. Your reference

AJBB/SPY/H.95

16NOV00 2584049-1 002624

P01/7700 0.00-0027893.7

2. Patent application number

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0027893.7

3. Full name, address and postcode of the or of each applicant (underline all surnames)

BENOIST GIRARD ET CIE
203, Boulevard de la Grande Delle - B.P.8.
14201 Hérouville-Saint-Clair Cédex,
France.

Patents ADP number (if you know it)

732 58 55 081

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

PROSTHETIC IMPLANT CEMENT DEFLECTOR
AND A SET OF COMPONENTS TO CARRY OUT A
PROSTHETIC IMPLANT EMPLOYING SUCH A
DEFLECTOR

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom
to which all correspondence should be sent
(including the postcode)

A.J. BRIDGE-BUTLER

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Holborn,
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Patents ADP number (if you know it)

14120045

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
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Date of filing
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7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

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- a) any applicant named in part 3 is not an inventor, or
- b) there is an inventor who is not named as an applicant, or
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See note (d))

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Description

14

Claim(s)

Abstract

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4

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Priority documents

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Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)

Request for preliminary examination and search (*Patents Form 9/77*)

Request for substantive examination (*Patents Form 10/77*)

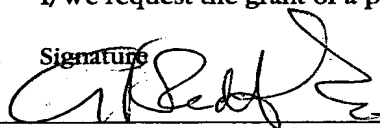
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11.

I/We request the grant of a patent on the basis of this application.

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Date



15 November 2000

12. Name and daytime telephone number of person to contact in the United Kingdom

A.J. BRIDGE-BUTLER

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PROSTHETIC IMPLANT CEMENT DEFLECTOR
AND A SET OF COMPONENTS TO CARRY OUT A PROSTHETIC IMPLANT
EMPLOYING SUCH A DEFLECTOR

This invention relates to a prosthetic implant cement deflector and to a set of components to carry out a prosthetic implant employing such a deflector and which are for use in prosthetic surgery when employing a cannulated phantom prosthesis or a cannulated surgical prosthesis which utilises a guide wire.

EP 0 995 410 shows a prosthetic implant cement deflector for use in prosthetic surgery when employing a cannulated phantom prosthesis and/or a prosthesis which has an insert portion and a bore adapted to receive a guide wire, and comprising a cement deflector element adapted to slide on said guide wire and which can act to seal the interface between the guide wire and the surface of the distal end of the bore. A phantom component is made larger than the actual implant so that a larger cavity is formed to provide a cement mantle of uniform thickness.

The present invention is a development from this concept and has a construction which provides additional advantages in as much that it can help to speed the surgeon's operating time and is easier to handle.

EP 0 705 579 shows a method and apparatus for implanting a prosthesis. The invention relates to a method of guaranteeing the position and thickness of an adequate cement mantle around the cemented implant and shows the use of a phantom component having a tapered insert portion. The phantom component is first inserted into a cavity which has been filled with bone chips which compress. A lining of cement is now applied to the cavity and a cannulated phantom is introduced into the opening.

The phantom is subsequently withdrawn from the cavity, the cement cavity inspected and the surgical process is finally implanted.

It has been found that using this technique can sometimes cause difficulties due to the passage of cement into the bore of the phantom within the gap between the phantom and the guide wire. Means to prevent these problems are provided by EP 0 995 410 and, as mentioned above, the present invention is intended to provide even easier operation of the technique and also of the technique of inserting, for example, a cannulated surgical prosthesis without the use of a phantom.

Preformed unperforated sheaths are shown in EP 0 457 464 B1 and EP 0 555 004 B1.

According to the present invention a prosthetic implant cement deflector for use in prosthetic surgery when employing a cannulated phantom prosthesis in combination with a cannulated or uncannulated surgical prosthesis or a cannulated prosthesis without a phantom prosthesis and in which each cannulated phantom prosthesis or cannulated prosthesis has an insert portion for location in the bone and a cannulation bore extending through said insert portion to receive a guide wire, and comprising a cement deflector element adapted to slide in sealing engagement on said guide wire and which can act to seal the interface between the guide wire and the surface of the distal end of the cannulation bore and has a preformed unperforated sheath adapted to extend over the insert portion from its distal end to a position at or adjacent to its proximal end.

Thus, this cement deflector extends not only from a point below the distal tip of the prosthesis insert portion

but over all its length within the bone when placed in position.

When the phantom is removed from the guide wire a smooth inner surface is provided by the extended sides of the deflector which are adapted to receive cement and when a cannulated or uncannulated prosthesis is inserted it provides a good fit.

There are also advantages when an uncannulated surgical prosthesis is inserted into the sheath after the phantom and guide wire have been removed.

As mentioned above, the cement deflector can also be used with a direct implantation of a surgical prosthesis along a guide wire, again being employed to prevent cement entering the cannulation bore and if desired to provide a void to allow the prosthesis to sink further.

The cement deflector element can be made from any convenient material, for example synthetic plastics material in the form of polymethylmethacrylate (PMMA).

Preferably X-ray markers are incorporated in the cement deflector element so that on subsequent X-ray examination any movement of the cement deflector element or relative movement between the element and the cannulated prosthesis within the cement deflector can be identified.

The X-ray markers can be in the form of spherical tantalum beads. Such markers can be used with a rontgen stereographometric analysis (RSA) to measure displacement of the prosthesis. The markers can also be used if X-ray active markers are applied to the bone, in this case to monitor relative positions of the sheath and bone.

The invention also includes a set of components to carry out a prosthetic implant and comprising a cannulated phantom prosthesis having an insert portion for location in a bone, a cannulation bore extending through said insert portion, a guide wire for sliding location in said cannulation bore, and a cement deflector element adapted for sliding engagement on said guide wire and which acts to seal the interface between the guide wire and the distal end of the cannulation bore and which is a preformed unperforated sheath which extends over the insert portion from its distal end to a position at or adjacent to its proximal end.

The set of components can also include an uncannulated prosthesis having an insert portion which is shaped and dimensioned to fit into said sheath together with a layer of cement to replace said cannulated phantom prosthesis and guide wire plus a centraliser with a void to allow the prosthesis to sink further.

In an alternative combination a cannulated surgical prosthesis can be included having an insert portion and a cannulation bore and having a cement deflector and which, on removal of said cannulated phantom prosthesis from said sheath is adapted to replace it on said guide wire, said cement deflector slidably engaging said guide wire and sealing the interface between the guide wire and the distal end of the cannulation bore in said prosthesis, and said insert portion thereon being shaped and dimensioned to fit into said sheath together with a layer of cement to replace the shallow prosthesis.

The cement deflector can be adapted to be secured to the distal tip of the portion of the cannulated prosthesis and it can be arranged to extend over at least part of the distal tip.

The invention can be performed in various ways and some embodiments will now be described by way of example and with reference to the accompanying drawings in which:

Figure 1 is a diagrammatic cross-section showing installation of a total hip prosthesis of known kind in a femur;

Figures 2 to 8 are part cross-sectional side elevations showing how a hip prosthesis of the kind shown in Figure 1 can come loose and be replaced by the method described in EP 0 705 579 but employing the present invention;

Figure 9 is a diagrammatic isometric view of a cement deflector according to the invention;

Figure 10 is an enlarged cross-sectional view of the distal end of a phantom prosthesis or surgical prosthesis in position on a guide wire with a cement deflector of the type shown in Figure 9 in place;

Figure 11 is an enlarged view of a cement deflector as employed by the cannulated surgical prosthesis shown in Figure 8;

Figure 12 is a similar view to Figure 11 of an alternative construction;

Figure 13 is a side view similar to Figures 11 and 12 of another alternative construction;

Figure 14 shows a further type of construction which are used on a cannulated surgical prosthesis of the kind shown in Figure 8;

Figure 15 shows how an X-ray marker can be incorporated in a wall of the cement deflector; and,

Figure 16 shows how a cement deflector of the kind shown in Figure 11 is lodged in a cement deflector of the kind shown in Figure 9.

Figure 1 shows an idealised primary hip intramedullary femoral prosthesis 1 of the straight tapering collarless polished design concept located in a femur 15. The prosthesis has a head 2, neck 3 and stem 4 and is held in place by bone cement indicated by reference numeral 16. The cortical bone 17 of the femur 15 retains some cancellous bone 18. The stem 4 is centralised in the canal by a centraliser 19 of known type and the canal is plugged by a bone plug 20.

Figure 2 illustrates what can happen when an implant, as shown in Figure 1, fails. The stem 4 together with the cement 16 break away from the bone and a pendulum effect is produced as shown by arrows 21. This causes severe damage within the bone so that all that is left is a thick cortex 22. A space 23 is created which becomes filled by fluids and fibrous tissues.

EP-A-0 555 004 shows an implant and a method by which the damaged joint can be repaired and this method will now be described further showing how it can be used in the present invention. The revision procedure commences as

shown in Figure 3 by removing the implant complete with cement and the fibrous tissue by first fitting a bone plug 30 and guide wire 31. Bone chips 32 are now added and compressed using an impactor or ram 33. The bone chips are built up layer by layer in the manner described in EP-A-0 555 004 and a stem phantom 34 is then introduced as shown in Figure 5 to readily compress the bone chips and form a cavity 35 which is most clearly shown in Figure 6.

The cavity 35 is now filled with cement 36, as shown in Figure 6, and this may be pressurised if desired. A cannulated phantom 50 having a bore 49 is now introduced into the opening 35, as shown in Figure 7, the insert portion or stem 51 having dimensions which are identical with or larger than those of a prosthesis which is intended to be fitted. The guide wire 31 provides means for accurately locating the phantom 50 in place. Unwanted cement from the filling 36 spills out as indicated by the arrows S.

Figure 7 also shows the present invention which comprises a prosthetic implant cement deflector 55 which is shown more clearly in Figures 9 and 10. Prior to placing the phantom 50 on the guide wire 31 the cement deflector 55 is placed on the phantom and moves down the guide wire 31 with it when the phantom is introduced into the opening. Because of the material from which the deflector is made it acts to seal the interface between the wire 31 and the surface of the bore 49 in the phantom. The deflector 55 can however slide down the wire 31.

Once the cement is cured or in a suitable state the phantom 50 is withdrawn from the cavity leaving the cement deflector 55 in place and forming a lining of cement 37 as shown in Figure 8. Because the deflector has acted to prevent cement entering the interface between the wire 31

and the bore 49 the phantom can be withdrawn without difficulty. To further assist withdrawal the phantom 50 will generally have a polished surface or alternatively be coated with a material which does not adhere to the sheath of the cement deflector 55.

The guide wire 31 is left in place and a further quantity of cement 39 is introduced into the cavity formed by the walls of the deflector sheath 55. A cannulated prosthesis 38 is then introduced down the guide wire 31. This prosthesis having an insert portion in the form of a stem, a neck 3 and head 2.

Prior to insertion of the cannulated prosthesis 38 a second cement deflector is fitted to its distal tip, this deflector being of the kind shown in Figure 11 to 14 and being the subject of EP 0 705 579. The construction of this type of deflector is described below and in Figure 8 a deflector of the type shown in Figure 14 is utilised. Prior to placing the cannulated prosthesis 38 on the guide wire 31 the second cement deflector, indicated by reference numeral 90, is placed on the wire 31. The wire is then engaged onto the distal tip of the prosthesis 38 which moves down the guide wire 31 and together with the second deflector 90 is introduced into the opening. Because of the material from which the deflector 90 is made it acts to seal the interface between the wire 31 and the surface of the bore in the cannulated prosthesis. As the cement deflector 90 approaches the distal end of the opening in the first cement deflector 55 the prosthesis 38 and second deflector 90 lodges in the deflector 38 as shown in Figure 16.

Once the cement is cured or in a suitable state, the guide wire is unthreaded from the intramedullary plug 30 and withdrawn through the deflectors and the prosthesis 38.

If desired the length of the stem of the prosthesis 38 can be arranged so that a void (not shown in Figure 8) is provided between the proximal end of the distal part of the deflector 55 and the distal end of the second deflector 60. This void allows the prosthesis 38 to sink further into the cement after curing as required and as is well known when using stems of this type.

Again, if desired, the first cement deflector 55 and/or the second cement deflector 60 can be provided with means, for example wings, so that it acts as a centraliser. The centraliser thus provided can also be shaped to provide the void between the second centraliser 60 and the upper part of the distal end of the centraliser 55 to accommodate subsequent downward movement. This centraliser will of course be inserted with the prosthesis 38.

In an alternative arrangement the cannulated prosthesis 38 can be replaced by an uncannulated prosthesis. The technique of insertion of this uncannulated prosthesis is similar to that described above but, prior to insertion, the guide wire 31 is unscrewed from the intramedullary plug 30 and removed. The second cement deflector is therefore not required because no guide wire is employed but a centraliser of the kind referred to above will usually be arranged on the distal tip of the uncannulated prosthesis and, again as referred to above, may be shaped to have a void into which the uncannulated prosthesis can sink further. The choice of whether to employ a cannulated or uncannulated prosthesis will depend upon the requirements of the surgeon at the time of the operation.

The stem geometry must allow an appropriate mechanism for the transmission of the load between the stem and the cement mantle so formed and an ideal hip stem for the use of this technique is of the type which incorporates a double tapered and polished stem form which effectively engages the cement mantle causing principally compressive transmission of load from the stem to the cement and thereby to the bone.

This selection is important if the surgeon chooses to use the original cement mantle formed by the phantom 50 with the definitive implanted stem. Inevitably manufacturing variations will result in a marginal mismatch between the mantle and the definitive stem. The use of the double tapered stem which allow tapered re-engagement to occur with the relative compliant and visco-elastic cement at body temperature results in the effective taper load transmission despite the manufacturing differences.

With existing techniques there can be inappropriate positioning of an implant within the cavity in the bone and they do not result in a uniform control thickness of cement mantle which would give a better mechanical performance of the cement. This is a particular advantage of the new method of insertion.

This method can also be used with a cannulated system of broaches for shaping the opening. They can be used to form a known cavity shape over and above the nominal size of the implant and further guarantees the mantle geometry.

A system of depth indicators can be used for example as shown in the technique described is US 5 192 283 and the depth indication system could also be used to position the phantom insert within the cavity formed by such broaches.

Figures 9 and 10 show a typical example of the present invention in more detail and which is for use as shown in Figures 7 and 8. The cement deflector 55 is made from polymethylmethacrylate (PMMA) and is provided with a hollow tapering bore 56 and has side walls indicated by reference numeral 57. The distal end 58 is in the form of a substantially circular tube which is of slightly less diameter than the guide wire 31 with which it is to be used. The overall dimensions of the deflector are such that they are adapted to extend over the insert portion, that is the stem of the phantom prosthesis or prosthesis with which it is to be used from its distal end to a position at or adjacent its proximal end and therefore acts as a sheath. The dimensions will clearly be seen from Figures 7 and 8.

The sheath is preformed and is unperforated throughout its length.

Figure 10 shows how the distal end 58 of the sheath distorts to accommodate the guide wire 31 and therefore acts as a close sealing fit on the wire. The sheath walls 57 closely engage the walls of the phantom prosthesis 50 or prosthesis 38 to provide the seal between the interface between the guide wire 31 and the distal end of the cannulation bore 49 in the phantom prosthesis or surgical prosthesis.

Figures 11 to 14 show examples of second cement deflectors which can be used on a cannulated surgical prosthesis which are to be engaged within the sheath provided by the first cement deflector 55 and which can be employed in the arrangement shown in Figure 8.

The cement deflector 60 is made from polymethylmethacrylate (PMMA) and is provided with a central bore 61 which is dimensioned to be a sliding fit on the

guide wire 31. The proximal end 62 of the deflector is recessed at the 63 to provide a push fit onto the distal end 64 of the cannulated prosthesis 38.

The primary advantage of the cement deflector is that when the phantom prosthesis or prosthesis is moved down the guide wire 31 the cement deflector 60 acts to prevent cement passing into the guide bore of the prosthesis around the guide wire 31. If the technique described with regard to Figure 8 is employed without such a cement deflector cement may pass up the guide wire 31 into the bore, and if the prosthesis is left in the opening until the cement part solidifies, it can be difficult to withdraw the guide wire due to the ingress of cement.

Figure 12 shows an alternative construction in which the same reference numerals are used to define similar parts but in this construction the deflector 70 is provided with an extended recess 71 the proximal end 72 of which is shaped and adapted, for example by being tapered, to engage the distal end 73 of the cannulated prosthesis 38. This construction is designed so that the distal end of the prosthesis 38 can extend into the proximal end 72 of the recess of the deflector 70 and a void 74 is provided by the lower part of the recess 71 into which the prosthesis 38 can subsequently sink. Thus, this construction, as shown in Figure 12, can be used to replace the construction shown in Figure 11 when used in the surgery described with regard to Figures 7 and 8 and overcomes the requirement for a centraliser.

Figure 13 shows another alternative construction in which the same reference numerals are used to indicate similar parts to those shown in Figure 11. In this construction however the cement deflector 80 has an external diameter which is substantially the same as the external

diameter of the distal end 59 of the prosthesis 38. The distal end of the prosthesis 38 is recessed as indicated by reference numeral 81 and receives a flange 82 formed on the end of the deflector. Thus, with this construction the deflector is held in place by the flange 82 during insertion and acts in a similar manner to the inserter described and shown in Figure 11.

Figure 14 shows a further construction of cement deflector 90 which can be used with a cannulated prosthesis. The same reference numerals are again used to describe similar parts to those shown in the previous Figures. The prosthesis 38 has a distal end 91 and a bore 92 to receive the guide wire 31. A cement deflector 93 is employed which has a bore 94 to receive the guide wire 31 and an enlarged bore 95 which is dimensioned to receive the distal end of the prosthesis 38, for example by being tapered.

This embodiment can be used either on the insertion into a newly prepared cavity in a bone or when used for replacement surgery.

The proximal portion of the enlarged bore 95 provides a void 96 in which the prosthesis 38 can subsequently sink. Once the prosthesis has been placed in position and the cement has set the guide wire 31 is of course removed but the cement deflector will once again have acted to prevent cement entering the interface between the wall of the bore 92 and the wire 31 thus allowing removal of the guide wire 31 without the usual difficulties.

Preferably the cement deflector 55, as shown in Figures 9 and 10, is provided with three X-ray markers, two at the upper end on the lateral and medial faces and a third at the distal end 58. Each of the markers is in the form of

a suitable radio-opaque bead 101 made, for example, from tantalum. Each bead is a press-fit in a recess 102 in the sheath wall 59.

The X-ray markers can be used for rontgen stereographometric analysis (RSA) and to indicate if there is any relative movement between the sheath and the prosthesis and, provided X-ray markers are also located in the bone, to show any relative movement between the sheath and the bone.

If desired, similar markers can be incorporated in the walls of the cement deflectors shown in Figures 11 to 14.

Although in the present description a technique as set forth in EP-A-0 555 004 is described the invention can equally be applied to a newly made cavity in a femur.

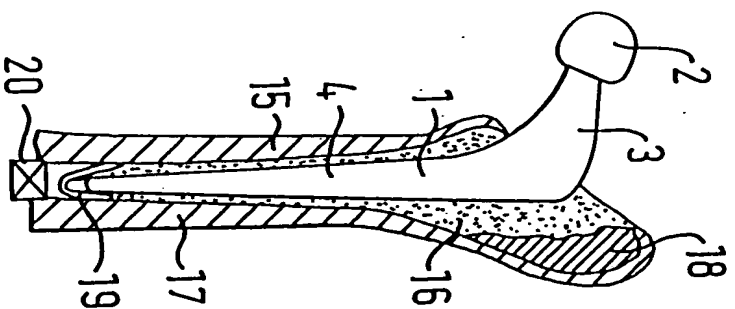


FIG. 1

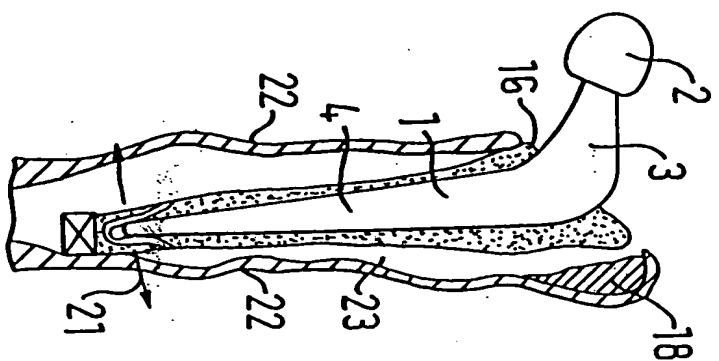


FIG. 2

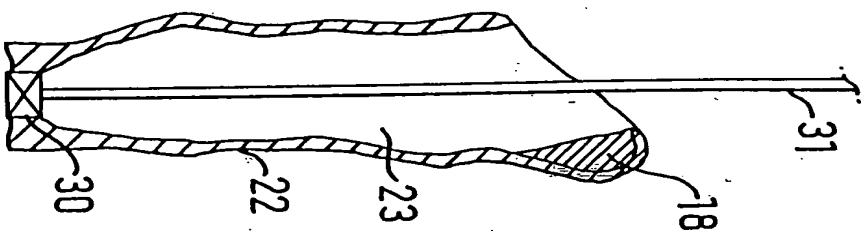


FIG. 3

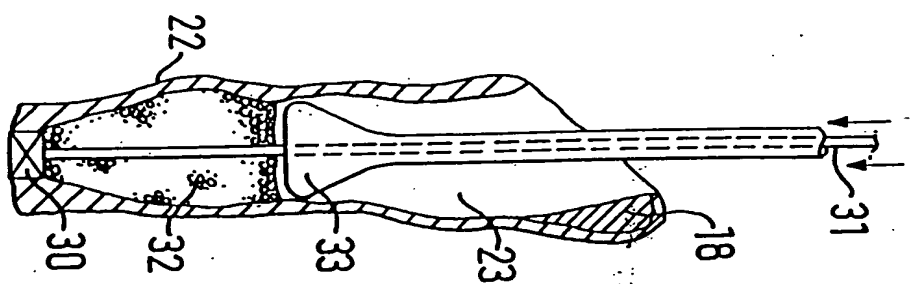


FIG. 4

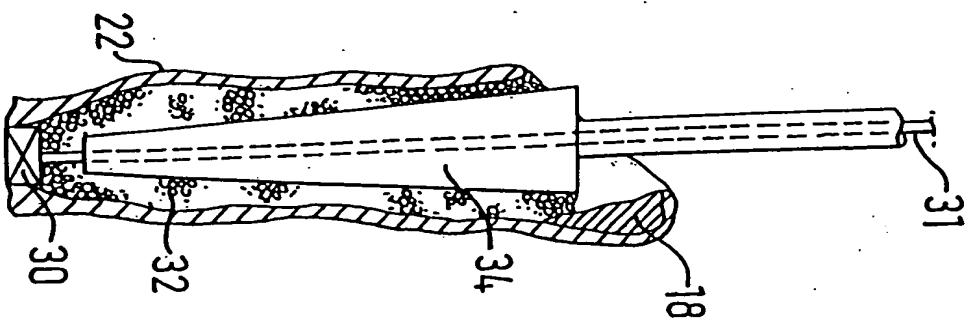


FIG. 5

